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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,964	07/11/2000	Walter Schubert	S159 1020	1538

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/04/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,964

Applicant(s)

SCHUBERT, WALTER

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-41 is/are pending in the application.
- 4a) Of the above claim(s) 34-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 26-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/1/03 has been entered.

Election/Restrictions

2. Applicant's election of Group I in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 26, the recitation of a "rail" is vague and indefinite because the intended meaning of this term is unclear. In addition, the recitation of a duct being defined by the object holder and the stretchable sheet and the rail is also vague and indefinite. In what way is the duct defined in this manner? The precise arrangement of the recited elements has not been adequately recited in the claim. Further, the recitation of the rail being mounted on the stretchable sheet to

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define the geometry of the duct is vague and indefinite because applicant has not recited in what manner these elements define the geometry of the duct. Applicant must more clearly recite the relationship of the elements of the device to each other.

6. Claim 33 is rejected as vague and indefinite for the recitation of a "stretchable strip". It is unclear what purpose this element serves in the recited device to deliver a liquid.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 26-28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Andrevski et al. (US Pat. 5,882,903). The reference discloses an assay system comprising a first assembly (object holder) comprising a reaction chamber (target structure) and a first fluid exchange channel that provides fluid communication to and from the reaction chamber. The system also comprises a second assembly for temperature control of the reaction chamber (col. 27, lines 35-54). In addition, the reaction chamber has a cover formed of a deformable material, wherein the cover is preferably formed of membrane films that are stretchable and flexible. The cover is, at a minimum, disposed indirectly on the object holder. When the cover is made of this deformable material, a plunger may be used to facilitate fluid transfer to a fluid exchange port that flows into an alignment chamber. The device of the reference may also comprise a pump. Also, the reference discloses that the assay system of the reference may take a number of configurations, including square and rectangular. Since a rail is simply interpreted as a rod-like

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support structure and the deformable cover inherently contacts the sides of the object holder, in the case of a square or rectangular configuration, the contact of the deformable cover to the sides of the object holder are sufficient to meet the limitation of a rail.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andreovski et al. (US Pat. 5,882,903) in view of Freeman (US Pat. 5,958,760).

Andreovski et al. teach an assay system, as previously discussed under 35 USC 102.

However, the reference does not teach the use of a Peltier element or a vessel.

Freeman teaches a sample-processing device comprising a support cell made up of a sealed chamber provided with a fluid inlet and outlet for introduction and removal of fluids used in sample processing (col. 2, lines 7-16). Typically, the support cell will be provided with a

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Peltier device, which may be used to heat or cool the cell to temperatures in the range of 4-100 degrees Celsius (col. 4, lines 13-22). The processing fluids are preferably held in reservoirs, each of which is attached to pump means (col. 4, lines 39-49 and col. 5, lines 3-11). After the processing fluids have been used, the waste is collected in a common waste duct that empties into a glass beaker (col. 10, lines 37-41). The duct of the reference is plastic, which is interpreted as stretchable.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the Peltier element and collection vessel of Freeman with the device of Andrevski et al. One would have been motivated to do so because the Peltier element of Freeman could have easily been used as the temperature control element of Andrevski et al. In addition, one would have been motivated to use the collection vessel of Freeman et al. with the device of Andrevski et al. to collect waste in a convenient manner.

12. Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrevski et al. (US Pat. 5,882,903) in view of Freeman (US Pat. 5,958,760), as applied to claims 29-30 above, and further in view of Teppke et al. (US Pat. 5,960,640).

Andrevski et al. and Freeman teach a modified sample-processing device, as discussed above. However, the references do not teach the use of a vessel Peltier element.

Teppke et al. teach a cryostatic microtome comprising a coolable specimen holder and knife holder. One way in which the specimen holder and knife holder can be cooled is through the use of Peltier elements in the specimen holder and knife holder (col. 2, lines 38-45). Capillaries are provided which are connected to the evaporator in the specimen holder (col. 6, lines 43-50).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a vessel Peltier element as taught by Teppke et al. with the modified device of Andrevski et al. and Freeman. Although Freeman only teaches the use of Peltier elements with support cells, incorporating one with the discharged liquid container simply represents an optimization of assay protocol. If one wished to use the discharged liquid for another purpose or at a later time, one would have been motivated to maintain the liquid at a suitable temperature, which can be done with a cooling Peltier element. For example, Teppke et al. uses two Peltier elements because such an arrangement allows for independent temperature control of various components of the device.

13. Claims 26-29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hancock et al. (US Pat. 5,716,825) in view of Maracas et al. (US Pat. 5,772,966).

Hancock et al. teaches a nucleic acid analysis system comprising a sample preparation compartment having access ports. The system may be constructed using a plastic polymer. The compartment is preferably enclosed by a cover formed of transparent material to allow observation of sample handling. The cover includes apertures spatially aligned with wells to form access ports when the cover is attached to the support. The device of the reference may also include valveless pumps. In addition, a Peltier element may be positioned to provide temperature control to the reaction zone of the device (Cols. 9-10). Since a rail is simply interpreted as a rod-like support structure and the cover inherently contacts the sides of the compartment, the contact of the cover to the sides of the compartment are sufficient to meet the limitation of a rail. However, the reference does not teach a cover made of a stretchable sheet.

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Maracas et al. teach a device, wherein the cover is preferably formed of a deformable material such as a flexible plastic, elastomer, or rubber.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the deformable material as the cover of Maracas et al. with the device of Hancock et al. Hancock only prefers that the cover to be transparent and does not limit the composition of the cover in any way. As such, one could have used a cover made of some plastic material as the cover with the device of the reference with a reasonable expectation of success. Since plastic is relatively cheap, use of this material may reduce the cost associated with the practice of the invention.

Conclusion

Claims 26-33 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641




CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641